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Filing Date: February 18, 2004

### REMARKS

Claims 91-95, 113-122, 127-141 were pending in this application. In this amendment, Claims 91, 113, 119, 120, 122, 127, 129, and 130 have been amended, and new dependent Claims 150-154 have been added. Therefore, Claims 91-95, 113-122, 127-140, and 142-154 are pending for further consideration.

Dependent Claims 150-154 are fully supported by the application as filed. Applicant submits that the newly added dependent Claims 150-154 are allowable for at least the same reasons as set forth below for the claim or claims from which they depend, and because they each recite further patentable distinctions over the cited references.

#### Personal Interview

Applicant thanks Examiner Sonnett for the courteous personal interview conducted on March 23, 2009 (summarized above).

#### Rejections Under 35 U.S.C. § 112

Claims 127 and 129 were rejected under 35 U.S.C. § 112, second paragraph, as lacking antecedent basis. These claims have been amended to address this rejection. Applicant requests that this rejection be withdrawn.

#### Rejections Under 35 U.S.C. § 102

Claims 91-95, 134, and 143 were rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,895,406 ("Gray"). Applicant disagrees with this rejection, but has made amendments set forth herein to expedite allowance. Applicant submits that none of amended Claims 91-95, 134, and 143 is anticipated by Gray under 35 U.S.C. 102(e) because Gray does not show every element of each claim arranged as in each claim. *See* MPEP §2131.

Amended Claim 91 recites a method of applying a radial force against a surface of a passageway with an expandable device, comprising:

providing an expandable device with a plurality of cells comprising a generally longitudinal wave-like first member and a generally longitudinal wave-like second member, at least one cell capable of being expanded between a stable contracted state in which the first and

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second members are generally in phase and at least one stable expanded state in which the first and second members are generally out of phase; and  
radially expanding the expandable device against a surface of the passageway such that the at least one cell is expanded from the stable contracted state to the at least one expanded state;  
*wherein one of the first and second members substantially retains its shape when the cell transitions from the contracted to the expanded shape.*

In contrast, the Gray device is constructed of a plurality of longitudinally extending bands with a continuous undulating structure in the unexpanded state. See Figure 3a of Gray. Gray states:

*In the course of expansion, as shown in FIG. 3, the wave shaped bands tend to become straighter. When the bands become straighter, they become stiffer and thereby withstand relatively high radial forces. FIG. 3 shows how radial expansion of the stent causes the fenestra to open up into a diamond shape with maximum stress being expended on the apices of the diamond along the longitudinal axis.*

Gray at 4:40-46.

A modification of the structure of Gray such that one of the bands substantially retained its shape, e.g., did not become straighter upon expansion, would result in a less stiff structure and thus would be contrary to the teachings of Gray.

For at least these reasons, Applicant requests allowance of amended Claim 91, as well as Claims 92-95, 134, and 143 which depend therefrom.

Claims 113, 118, 135, 139, and 141 were rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,643,314 ("Carpenter"). Applicant disagrees with this rejection, but has made amendments set forth herein to expedite allowance.

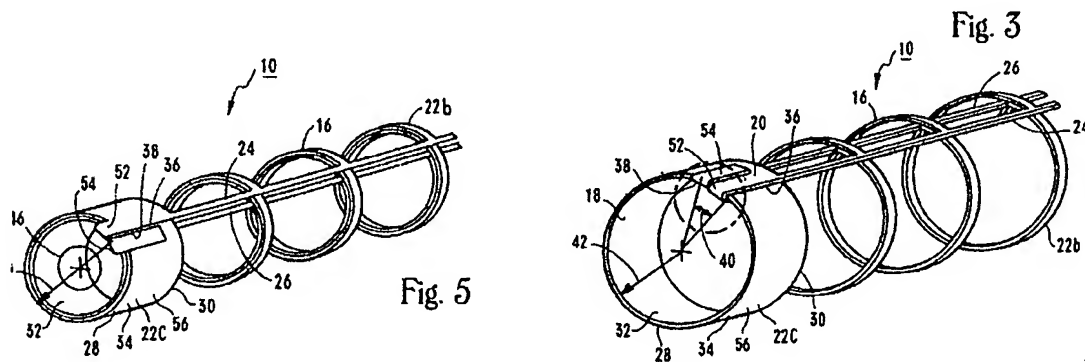
None of Claims 113, 118, 135, 139, and 141 is anticipated by Carpenter under 35 U.S.C. 102(e) because Carpenter does not show every element of each claim arranged as in each claim. See MPEP §2131.

In particular, amended Claim 113 recites a method of stabilizing an unsupported section of a passageway, comprising:

- providing an expandable device having one or more cells, each of the cells comprising first and second arcuate members;
- placing the device at a position in the passageway while in a first stable state;
- applying a radially outward force to the expandable device to expand the one or more cells to a transition point defining a geometry of the one or more cells at which no additional force is necessary to further expand the one or more cells; and
- permitting the one or more cells to continue to expand beyond the transition point without the application of additional force;

wherein at least a portion of the first arcuate member changes from a generally concave shape to a generally convex shape when the one or more cells expand beyond the transition point.

In contrast, Carpenter describes a self-expanding stent 10 that includes a cylinder 16 formed from a series of series of radial bands 22a, 22b, and 22c. Figures 5 and 3 show contracted and expanded conditions respectively. (Figure 3 has been modified to exclude certain dotted lines related to the enlarged detail view of Figure 3A.)



These figures clearly show that Carpenter does not include, *inter alia*, “at least a portion of the first arcuate member **changes from** a generally concave shape to a generally convex shape when the one or more cells expand beyond the transition point.” Accordingly, Applicant requests that Claim 113 be allowed over Carpenter. Applicant also respectfully allowance of Claims 118, 135, 139, and 141, which depend from Claim 113 and are therefore allowable for at least the same reasons that Claim 113 is allowable.

#### Rejections Under 35 U.S.C. § 103

Claims 119-122, 127-129, 136, 137, and 144 were rejected in the Office Action under 35 U.S.C. § 103(a), as being obvious in view of Gray, discussed above.

Applicant traverses the rejection of Claim 119 in view of Gray. Nevertheless, to expedite allowance, Applicant has amended Claim 119 to recite a method for installing a liner within a tubular passageway, comprising:

providing an expandable device with *a plurality of bistable cells*, each of the bistable cells comprising first and second arcuate members, each cell being capable of assuming a stable collapsed configuration in which the first and second arcuate members are in phase and *being capable of isothermally expanding to* a stable expanded configuration in which the first and second arcuate members are out of phase, the expandable device having a generally tubular shape; and

supporting an expandable liner element with the expandable device.

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As noted above, Claim 119 has been amended to clarify that the expandable device comprises cells capable of assuming a stable collapsed configuration and being capable of isothermally expanding to a stable expanded configuration. Applicant submits that Gray does not disclose or suggest the method of amended Claim 119 for at least this reason. Applicant therefore requests that the rejection of Claims 119, and 120-121, 136, 140, and 144 which depend therefrom, be withdrawn.

Applicant traverses the rejection of Claim 122 in view of Gray. Claim 122 recites a method of isolating a portion of a passageway, comprising:

inserting within the passageway an expandable multistable device formed by one or more of cells that permit the expandable device to be selectively actuated between a contracted state and at least one expanded state, each of the cells comprising first and second wave-like portions;

expanding the one or more cells from a stable collapsed configuration in which the first and second wave-like portions are in phase to a stable substantially completely expanded configuration, in which the first and second wave-like portions are out of phase, wherein there are no stable configurations between the stable collapsed configuration and the stable expanded configuration; and

isolating a portion of the passageway with the expandable device.

In contrast, as discussed above, the Gray device is constructed of a plurality of longitudinally extending bands with a continuous undulating structure in the unexpanded state (see Figure 3a of Gray) that straighten in the expanded state. See Gray at column 4, lines 40-46, stating that, “[i]n the course of expansion, as shown in FIG. 3, *the wave shaped bands tend to become straighter*,” and “[w]hen the bands become straighter, they become *stiffer* ...” (emphasis added)

Thus, because Gray states that the wave shaped bands tend to become straighter in the course of expansion, it would be contrary to the teaching of Gray to modify the structure of Gray such that the first and second portions (which are “wave-like” in both the collapsed configuration and the expanded configuration in Claim 122) are both wave-like and out of phase in the expanded configuration.

First, contrary to Gray’s bands which become straighter during expansion, the first and second wave-like portions of Claim 122 are by definition not straight in the expanded configuration. Further, Gray does not ever disclose or suggest that the bands are out of phase in

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the expanded configuration. To the contrary, as discussed above, Gray states that, in the course of expansion, the wave shaped bands tend to become straighter.

For at least these reasons, Applicant requests that amended Claim 122, as well as Claims 127-129, and 137 which depend therefrom, be allowed over Gray.

Claim 140 was rejected in the Office Action under 35 U.S.C. § 103(a), as being unpatentable over Gray in view of U.S. Patent No. 4,886,062 ("Wiktor").

Claim 140 is allowable over Gray in view of Wiktor at least because Wiktor does not overcome Gray's failure to disclose or suggest all of the limitations set forth in Claim 119, from which Claim 140 depends. Claim 119 has been discussed above. Claim 140 is allowable because of the limitations set forth therein, combined with the limitations of Claim 119, would not have been obvious to one of ordinary skill in the art in view of Gray and Wiktor at the time of the inventions.

Claims 114-117 were rejected in the Office Action under 35 U.S.C. § 103(a), as being unpatentable over Carpenter.

Claims 114-117 are allowable over Carpenter because, as discussed above with regard to Claim 113, Carpenter does not disclose, suggest, or render obvious all of the limitations of Claim 113 from which Claims 114-117 depend, and because Claims 114-117 set forth further patentable distinctions that are not disclosed, suggested, or rendered obvious by Carpenter. Claims 114-117 are allowable because of the limitations set forth therein, combined with the limitations of Claim 113, would not have been obvious to one of ordinary skill in the art in view of Carpenter at the time of the inventions.

Claims 130-133, 138, 145, 146, and 148-149 were rejected in the Office Action under 35 U.S.C. § 103(a), as being obvious in view of the combination of Gray and U.S. Patent No. 5,383,926 ("Lock").

Applicant disagrees with this rejection and traverses on several grounds. First, Applicant submits that the combination of Gray and Lock is improper and would not have been considered by one of ordinary skill in the art because both Gray and Lock teach away such a combination. In particular, both Gray and Lock teach away from combining the connecting strips of Lock with the stent of Gray.

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The Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 (“Examination Guidelines”) at MPEP §2141 et seq., states at p. 2100-130 (MPEP §2143) that “combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art” (citing *United States v. Adams*, 383 U.S. 39, 51-52, 148 USPQ 479, 483-84 (1966)) and that, “[w]hen the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious.” (citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007)).

As discussed in greater detail below, Applicant submits that Lock teaches away from this combination by disclosing that its device requires a lateral gap or slit along the entire length of the sleeve member, and Gray teaches away from this combination by teaching that preserving the structural integrity of the stent requires ensuring a sufficient number of circumferential bands and links.

In particular, as listed below, Lock discloses the need for the lateral slot resulting in the C-shape of the sleeve. Lock states:

**A further feature of the present invention allows for circumferential growth of the vessel by the presence in the sleeve member of a lateral slot, giving a C-shape to the sleeve. Therefore a section of the vessel wall located in the opening of the “C” is not adhering to the endoprosthesis thereby allowing circumferential growth in that region.**

Col. 2, lines 33-39.

See also, Lock at col. 3, lines 52-58, stating that, “[i]n a preferred embodiment, the sleeve member 12 includes at least one lateral slot 24 in the wall 14 parallel to the longitudinal axis 20 and extending between the opposite ends 16, 18” and that “[t]he opposing edges 26, 28 define an open region 30 between them.” (underlining added). Thus, Lock teaches away from the uninterrupted tubular structure disclosed in Gray.

Gray states that “[a] plurality of links maintains the bands in a tubular structure” and that, “[i]n a further embodiment, each longitudinally disposed band of the stent is connected at a plurality of periodic locations by a short circumferential link to an adjacent band.” Gray 1:53-57 (underlining added). Gray also states that the optimization of strain and “pop” pressure is

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achieved by, among other things, preserving a sufficient number of bands and links to preserve the structural integrity of the stent after expansion. See col. 4, lines 54-57.

In sum, because Gray teaches away from the lateral slot along the entire length of the stent that Lock requires for operability of its device, it is beyond the skill of one of ordinary skill in the art to determine how the device of Lock, having the expansion limiting strips, could operate as described in Lock if the sleeve member from Gray does not have a lateral slot. Therefore, it would not have been obvious to one of ordinary skill in the art to combine Gray and Lock as set forth in the Office Action.

Further, Gray and Lock, if combined, do not disclose all the limitations of Claim 130. Claim 130 recites a method of expanding an expandable device in a passage way, comprising:

providing an expandable device having at least one cell, the at least one cell comprising first and second members, at least a portion of the second member(s) being more pliable than the first member(s);

positioning the expandable device in a passage way;

applying a radially outward force to the expandable device to expand the at least one cell to *a transition point of the at least one cell* defining a geometry of the at least one cell beyond which no additional force is needed to further expand the least one cell, at least a portion of the at least one cell moving between a generally concave state and a generally convex state at the transition point; and

permitting the at least one cell to continue to expand beyond the transition point without the application of additional force.

In contrast, in connection with the connecting strips 22, Lock states:

**When necessary, to allow expansion to a second circumference of diameter d" to accommodate vessel growth or prevent restenosis, the connecting strips can be disjoined. In one embodiment the balloon catheter is reinserted and inflated at a pressure four to ten atmospheres causing the connecting strips to rupture or break allowing the sleeve member 12 to further expand, thereby enlarging the open region 30, or C-shape. This allows the sleeve member 12 to conform to the expanded circumference of the body vessel as for example in the pediatric patient. In an embodiment where the connecting strip 22 is formed from an absorbable suture material and the sleeve member 12 is formed in a self-expandable configuration, when the suture dissolves the sleeve member 12 can self-expand to conform to the expanded configuration.**

Lock at 5:18-34.

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This passage clearly states that the rupturing of the strips 22 allows for the further expansion of the device, and does not describe that the rupturing of the strips 22 is a result of any aspect of any of the cells of the sleeve member 12. Rather, in one case, the strips 22 rupture at a specified balloon pressure. There is no discussion of how this range of balloon pressure affects the structure of the sleeve 12 up to or at the point of rupture. In the case of the self-expanding embodiment, the strips 22 are said to dissolve, which again is completely independent of the geometry of the cells of the sleeve 12. For at least this reason, Claim 130 is not rendered obvious by the combination of Gray and Lock.

For at least these reasons, Claim 130 and Claims 132-133, 138, 145, 146, and 148-149 which depend therefrom are not rendered obvious by Gray and Lock. Applicant requests that Claims 130-133, 138, 145, 146, and 148-149 be allowed.

Claim 147 was rejected in the Office Action under 35 U.S.C. § 103(a), as being unpatentable over Gray in view of Lock and further in view of U.S. Patent No. 5,496,365 ("Sgro").

Claim 147 is allowable over Gray in view of Lock and Sgro at least because Lock and Sgro do not overcome Gray's failure to disclose or suggest all of the limitations set forth in Claim 130, from which Claim 147 depends. Claim 130 has been discussed above. Claim 147 is allowable because of the limitations set forth therein, combined with the limitations of Claim 130, would not have been obvious to one of ordinary skill in the art in view of Gray, Lock, and Sgro at the time of the inventions.

*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not



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reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

| Docket No.   | Serial No. | Title  | Filed       |
|--------------|------------|--|-------------|
| PARGN.002C1  | 10/270,771 | BISTABLE SPRING CONSTRUCTION FOR A STENT AND OTHER MEDICAL APPARATUS             | 11-Oct-2002 |
| PARGN.2C1CP1 | 11/317,495 | DEVICE COMPRISING BIODEGRADABLE BISTABLE OR MULTISTABLE CELLS AND METHODS OF USE | 22-Dec-2005 |
| PARGN.2C1CP2 | 11/391,940 | FRACTURE-RESISTANT HELICAL STENT INCORPORATING BISTABLE CELLS AND METHODS OF USE | 29-Mar-2006 |

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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